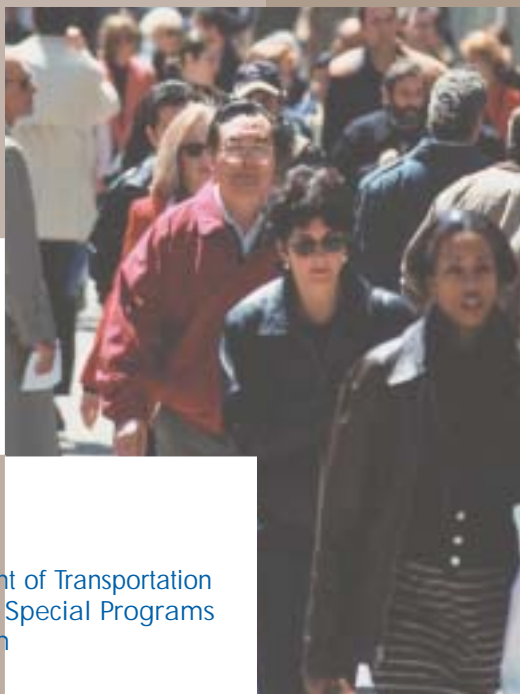


Infectious

HOW TO
TRANSPORT
Substances



U.S. Department of Transportation
Research and Special Programs
Administration

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HOW TO TRANSPORT INFECTIOUS SUBSTANCES

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What is an Infectious Substance? (§ 173.134(a)(1))

An **infectious substance** (Division 6.2) is a material known to contain or suspected of containing a pathogen that causes disease in humans or animals. An infectious substance must be assigned a risk group.

What is a Risk Group? (§ 173.134(a)(6))

A **risk group** (RG) is a number from 1 (low risk) to 4 (high risk) that represents the rank of a microorganism's ability to cause injury through disease to an individual and community based on its severity, mode and ease of transmission, and reversibility through available agents and treatment.

Why Are Infectious Substances Regulated in Transportation?

Congress requires the Secretary of Transportation to prescribe regulations for the safe transportation of hazardous materials in commerce to ensure public safety and minimize risks in transportation. An infectious substance is a hazardous material. It must meet the requirements of the Department of Transportation's Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) before being offered for transportation by rail, water, air, or highway.



Definitions (§§ 173.6 and 173.134 (a))

The following are Division 6.2 materials if they meet the definition of an infectious substance.

Biological Product - a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals.

Cultures and Stocks - a material containing a RG 2, 3, or 4 infectious substance prepared and maintained for growth and storage.

Diagnostic Specimen - any human or animal material, other than a RG 4 infectious substance, being transported for diagnostic or investigational purposes, but excluding live infected humans or animals.

Material of Trade (MOT) - a Division 6.2 material that is a diagnostic specimen, biological product, or regulated medical waste, and carried on a motor vehicle for at least one of three purposes described under the MOT definition in § 171.8. A RG 4 infectious substance may not be transported as a MOT.

Regulated Medical Waste (RMW) - a waste or reusable material known to contain or suspected of containing a RG 2 or 3 infectious substance and generated in the diagnosis, treatment, or immunization of human beings or animals, research related to these activities, or the production or testing of biological products.

Sharps - any object that is or may become contaminated with a pathogen through handling or during transportation that is capable of cutting or penetrating skin or a packaging material.

Toxin - a Division 6.1 (poisonous) material from a plant, animal, or bacterial source that contains or is contained in a Division 6.2 material.

Used Health Care Product - a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that is contaminated with potentially infectious body fluid or material. It does not meet the definition of a diagnostic specimen, biological product, or RMW.

What Items Are Excepted from the Infectious Substance Definition? (§ 173.134(b) and (d))

The following Division 6.2 materials are excepted from regulation under the HMR if they do not meet the definition of a hazardous substance, hazardous waste, marine pollutant, or other hazard class.

- A material containing a RG 1 infectious substance.
- A material that contains no pathogen or in which the pathogen has been neutralized or inactivated.
- A biological product subject to federal approval, permit, or licensing requirements.
- Blood collected for transfusion or testing or to make blood products, prepared blood products, tissues or organs intended for transplant operations, and human cell, tissue, and cell- and tissue-based products regulated under the authority of the Public Health Service Act or the Food, Drug, and Cosmetic Act. If believed to contain an infectious substance, a sample of blood collected for transfusion, or to make a blood product, that is transported for testing must comply with the requirements in § 173.199.
- A diagnostic specimen or biological product transported by a private or contract carrier in a motor vehicle used exclusively for these materials. The vehicle may include properly packaged medical or research equipment and lab products.
- Laundry or medical equipment, except medical equipment transported for disposal, that conforms to the regulations in 29 CFR 1910.1030.
- A living person.
- Any waste or recyclable material, other than RMW, that is:
 - S garbage and trash from a residence, including households and hotels, etc.,
 - S sanitary waste, sewage or sewage sludge or compost,
 - S animal waste generated in husbandry or food production, or,
 - S medical waste generated from households and transported under applicable state, local, or tribal requirements.
- Corpses, remains, and anatomical parts intended for interment, cremation, or medical research.
- Forensic material transported on behalf of U.S. government, state, local, or Indian tribal requirements, except material known or suspected to contain an infectious substance that is:
 - S a RG 2 or 3 infectious substance shipped in § 173.24 packaging, or



- S a RG 4 infectious substance or a select agent listed in 42 CFR Parts 72 and 73, as amended by the Department of Health and Human Services, shipped in packaging that:
 - ◆ meets § 178.609 test requirements, and
 - ◆ has a secondary packaging marked with a BIOHAZARD symbol meeting the specification under 29 CFR 1910.1030(g)(1)(i), an itemized list of contents between the secondary and outer packaging, and an outer packaging.
- Environmental microbiological samples known or suspected of being non-infectious collected to evaluate occupational and residential exposure risks.
- Agricultural products and food, as defined in the federal Food, Drug, and Cosmetics Act.

Requirements for Transporting Infectious Substances (§ 173.196)

Division 6.2 Packaging

- **A triple packaging that includes:**

- S a watertight primary receptacle,
- S a watertight secondary packaging,
- S an outer packaging at least 100 mm (3.9 inches) in dimension,
- S for a liquid, an absorbent material between the primary receptacle and secondary packaging,
- S an itemized list of contents between the secondary and outer packaging,
- S a primary receptacle or secondary packaging capable of withstanding an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi), and
- S a primary receptacle or secondary packaging capable of withstanding temperatures ranging from -40° C to +55° C (-40° F to +131° F).

- **Meets the test requirements in § 178.609**

- **Additional requirements:**

- S Lyophilized (freeze dried) - primary receptacle is a flame-sealed glass ampule or rubber-stopped glass vial fitted with a metal seal.
- S Liquid or solid infectious substances:
 - ◆ Ambient or higher temperature: glass, metal, or plastic primary receptacle with a leakproof seal.
 - ◆ Refrigerated or Frozen: ice or dry ice outside the secondary packaging or in an overpack with interior supports that secure the secondary packaging.

- ◆ Liquid nitrogen:
 - S primary receptacle and secondary packaging maintain their integrity at the liquid nitrogen temperature, and the temperatures and pressures of air transport if refrigeration is lost;
 - S metal vented vacuum insulated vessels or flasks (safety relief valves or similar devices in the vent lines are prohibited);
 - S fill and discharge openings protect against foreign material; and
 - S packaging design prevents release of liquid nitrogen in all orientations.
- Live animals: transported under the terms and conditions of an approval (see 49 CFR Part 107, Subpart H).
- Body parts, organs, or whole bodies: packaging meets § 173.196(a) and (b), or § 173.197.

Required

Marking

- Hazardous material: 49 CFR Part 172, Subpart D.
- UN standard non-bulk packaging: § 178.503(f).

Labeling - INFECTIOUS SUBSTANCE label - § 172.432.

Shipping Paper - 49 CFR Part 172, Subpart C.

Emergency Response Information - 49 CFR Part 172, Subpart G.

Formal Training and Recordkeeping - 49 CFR Part 172, Subpart H.



Requirements for Transporting Diagnostic Specimens (§ 173.199)

Diagnostic Specimen Packaging

- **Primary receptacle:**
 - S packed so it cannot break, be punctured, or leak into the secondary packaging.
 - S fragile primary receptacles in a single secondary packaging must be individually wrapped or separated to prevent contact.
 - S if containing a **liquid** -
 - ◆ leakproof with a capacity of 500 mL (16.9 ounces) or less,
 - ◆ absorbent material sufficient to absorb all the liquid between the primary and secondary packaging.
 - S if containing a **solid** -
 - ◆ sift proof primary receptacle with a capacity of 500 g (1.1 pounds) or less.
- **Secondary packaging:**
 - S secured in outer packaging with cushioning material that will maintain its protective properties and that of the outer packaging should the contents leak.
 - S if containing a **liquid** -

- ◆ leakproof,
- S If transported by **aircraft** -
 - ◆ primary receptacle or secondary packaging capable of withstanding without leakage an internal pressure producing a pressure differential of 95 kPa (0.95 bar, 14 psi) or less.
- S if containing a **solid** -
 - ◆ leakproof.
- **Outer packaging:**
 - S the completed package is capable of successfully passing the drop test in § 178.603 from a height of at least 1.2 meters (3.9 feet),
 - S may not exceed 4 L (1 gallon) for liquids, and
 - S may not exceed 4 kg (8.8 pounds) for solids.

Required

Marking - Hazardous material: "Diagnostic Specimen" on the outer packaging.

Formal Training and Recordkeeping - each person who offers or transports a diagnostic specimen for transportation must know about the requirements of § 173.199.

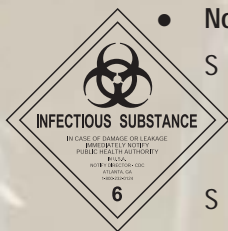
Not required

Labeling (an INFECTIOUS SUBSTANCE label), **Shipping Paper**, **Emergency Response Information**.

Requirements for Transporting Regulated Medical Waste (RMW) (§§ 173.134(c) and (d), and 173.197)

RMW Packaging - Non-bulk

- **Non-specification (§ 173.134(c))**
 - S Other than a waste culture or stock:
 - ◆ rigid,
 - ◆ meets §§ 173.24, 173.24a, and 29 CFR 1910.1030, and
 - ◆ offered for transportation by private or contract motor carrier.
 - S RG 2 or 3 infectious substance waste culture or stock:
 - ◆ rigid,
 - ◆ meets §§ 173.24, 173.24a, and 29 CFR 1910.1030,
 - ◆ offered for transportation by private or contract motor carrier in a dedicated RMW vehicle, and
 - ◆ can include medical or clinical equipment and lab products when properly packaged and secured.
- **UN Standard (§ 173.197(b))**
 - S rigid,
 - S meets Packing Group (PG) II performance requirements in 49 CFR Part 178, and
 - S puncture-resistant for sharps and those with fluid residue.



RMW Packaging - Bulk (§ 173.197(c), (d), and (e))

- **Authorized outer packagings:**

- S UN standard Large Packaging (Metal: 50A, 50B, or 50N; Rigid plastic: 50H).
 - ◆ design, testing, and re-qualification requirements for intermediate bulk containers under 49 CFR Part 178, Subpart O;
 - ◆ rigid inner packagings for liquids;
 - ◆ enough absorbent material in a location to absorb all liquid present; and
 - ◆ sharps packagings capable of retaining liquid.Non-specification wheeled cart (Cart).
 - ◆ solid one-piece body with a volume of 1,655 L (437 gallons) or less;
 - ◆ metal, rigid plastic, or fiberglass with a fitted lid;
 - ◆ meets drop test in § 178.603 at the PG II performance level; and
 - ◆ inner packaging placed and restrained in a way that minimizes breakage.
- S Non-specification bulk outer packaging (BOP).
 - ◆ metal or fiberglass with a volume of 3.5 cubic meters (123.6 cubic feet) to 45 cubic meters (1,590 cubic feet);
 - ◆ fully welded or seamless bottom and side joints;
 - ◆ rigid and weatherproof top; and
 - ◆ closure on each opening to prevent water from entering;
 - ◆ leakproof in the upright position, and can contain at least 300 L (79.2 gallons) with closures open;
 - ◆ inner packagings placed in a way that minimizes breakage;
 - ◆ plastic film bags are separated by a rigid barrier or divider from rigid inner packagings; and
 - ◆ Division 6.1 and Class 7 chemotherapeutic waste, untreated cultures and stocks of RG 2 or 3 organisms, unabsorbed liquids, and sharps may be transported if separated as provided in § 173.197(d)(3)(v).
- S General requirements for Carts and BOPs:
 - ◆ outer packagings have smooth, non-porous interior surfaces free of defects;
 - ◆ used exclusively to transport RMW;
 - ◆ disinfected before reuse;
 - ◆ not permitted: Division 6.1 (toxic) or Class 7 (radioactive) waste, unless it is chemotherapeutic waste, and untreated RG 4 cultures and stocks;
 - ◆ requires rigid non-bulk packaging that conforms with §173.197(a): Division 6.1 and Class 7 chemotherapeutic waste,

untreated RG 2 or 3 cultures, unabsorbed liquids, and sharps containers.

- **Authorized inner packagings:**

- S Solids:

- ◆ plastic film bag marked to certify it meets puncture-resistance and tear-resistance tests (e.g., marked with "ASTM D 1709-01" and "ASTM D 1922.00a"),
 - ◆ must pass closed inverted bag test, and
 - ◆ each film bag may not weigh more than 10 kg (22 pounds) when filled.

- S Liquid:

- ◆ rigid inner packaging meeting the requirements in § 173.197(a), and
 - ◆ each inner packaging may not contain more than 19 L (5 gallons).

- S Sharps:

- ◆ puncture-resistant container,
 - ◆ capable of passing the drop test at the PG II performance level if larger than 76 L (20 gallons), and
 - ◆ may be reused if:
 - ◆ approved by the Food and Drug Administration for reuse,
 - ◆ marked for reuse, and
 - ◆ disinfected before reuse.

Required Marking

- Hazardous material: 49 CFR Part 172, Subpart D.
- UN standard package:
 - S Non-bulk: § 178.503.
 - S Large: UN Recommendations, Chapter 6.6.
- Bulk Package:
 - S BIOHAZARD symbol meeting the specification under 29 CFR 1910.1030(g)(1)(i), and applied as required in §172.323.



Labeling - an INFECTIOUS SUBSTANCE label.

Shipping Paper - 49 CFR Part 172, Subpart C.

Emergency Response Information - 49 CFR Part 172, Subpart G.

Formal Training and Recordkeeping - 49 CFR Part 172, Subpart H.

Not required

Labeling - an INFECTIOUS SUBSTANCE label is not required on a § 173.134(c) packaging with a BIOHAZARD marking.

Used Health Care Products (§ 173.199(d))

A health care product removed from its original packaging and being returned to the manufacturer or its designee is excepted from the HMR as a used health care product (product) when packaged as follows. A RG 4 infectious substance may not be transported as a used health care product.

Packaging

- S product is drained of liquid,
- S product is placed in a watertight primary container,
- S packaging is capable of retaining without puncture a product that can cut or penetrate skin or packaging material,
- S a watertight secondary container,
- S an outer packaging with sufficient cushioning material to prevent movement of the secondary packaging, and
- S an itemized list of contents in between the secondary and outer packaging.

Required

Marking - primary and secondary containers must be marked with the BIOHAZARD symbol under 29 CFR 1910.1030(g)(1)(i).

Formal Training and Recordkeeping - each person who offers for transportation or transports a used health care product must know about the requirements of § 173.199.

Not required

Labeling - an INFECTIOUS SUBSTANCE label.

Emergency Response Information; Shipping Paper.

The product is excepted from all other HMR requirements when returned to the manufacturer or its designee, and packaged as required under § 173.199(d).

Material of Trade (§ 173.6)

Packaging

Diagnostic specimen, biological product, or regulated medical waste

! Combination packaging:

- S For liquids:
 - ◆ leak-tight inner packaging,
 - ◆ leak-tight outer packaging, and
 - ◆ enough absorbent material to absorb the entire contents of the inner packaging.
- S For sharps:
 - ◆ rigid, and
 - ◆ puncture- and leak-resistant inner packaging.

! Outer packaging:

- S strong,
- S tight,
- S securely closed, and
- S secured against movement.

! Capacity limitations:

- S inner packagings with a gross mass or capacity of:
 - ◆ 0.5 kg (1.1 pound) or less, or
 - ◆ 0.5 L (17 ounces) or less.
- S an outer packaging having a gross mass or capacity of:
 - ◆ 4 kg (8.8 pounds) or less, or
 - ◆ 4 L (1 gallon) or less; or
- S a single inner packaging within a single outer packaging with a gross mass or capacity of:
 - ◆ 16 kg (35.2 pounds) or less, or
 - ◆ 16 L (4.2 gallons) or less.

For RMW

! Capacity limitations:

- S inner packagings with a gross mass or capacity of:
 - ◆ 4 kg (8.8 pounds) or less, or
 - ◆ 4 L (1 gallon) or less.
- S a single inner packaging within a single outer packaging with a gross mass or capacity of:
 - ◆ 16 kg (35.2 pounds) or less, or
 - ◆ 16 L (4.2 gallons) or less.



- ! **Aggregate gross weight** of total MOT on a vehicle cannot exceed 200 kg (440 pounds).

Required

Marking - 49 CFR Part 172, Subpart D.

Labeling - 49 CFR Part 172, Subpart E.

Not required

Shipping Paper, Emergency Response Information, Formal Training and Recordkeeping.

Security Plans (§§ 172.800 and 172.804)

Shippers and carriers of the following are required to develop and implement a security plan:

- a highway route-controlled quantity of a Class 7 (radioactive) material in a motor vehicle, rail car, or freight container;
- more than 25 kg (55 pounds) of a Division 1.1, 1.2, or 1.3 explosive in a motor vehicle, rail car, or freight container;
- more than 1 L (1.06 quarts) per package of a material poisonous by inhalation, Hazard Zone A;
- a shipment of hazardous material in a bulk packaging with a capacity of 13,248 L (3,500 gallons) or more for liquids or gases, or more than 13.24 cubic meters (468 cubic feet) for solids;
- a shipment in non-bulk packagings with a gross weight of 2,268 kg (5,000 pounds) or more of one class of hazardous material that is required to be placarded under 49 CFR Part 172, Subpart F;
- a **select agent or toxin** regulated by the Centers for Disease Control and Prevention under 42 CFR Part 73; or,
- a quantity of material that requires a placard.



Incident Reporting (§§ 171.15 and 171.16)

You must report any release of an infectious substance in transportation to the Department of Transportation. See § 171.15 for telephonic report requirements and § 171.16 for written report requirements.

Exception (§ 173.199(a)): For a diagnostic specimen, an incident report is required only when a release occurs during transportation by aircraft.

Reuse (§§ 173.28(f) and 177.843(d))

Containers and transport vehicles: An infectious substance container or transport vehicle must be cleaned before reuse by any means that will neutralize the infectious substance the packaging previously contained.

Exception: The secondary or outer packaging do not need to be disinfected prior to reuse if the primary receptacle did not leak. The transport vehicle does not need to be disinfected unless a Division 6.2 material is released from its packaging.

Placards

No placards are required for Division 6.2 materials.



Where to Learn More

For information about other Hazmat Publications

Write:

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